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| SERIAL NUMBER | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---------------|-------------|----------------------|---------------------|
|---------------|-------------|----------------------|---------------------|

08/000,716 01/05/93 ALIZON

M 3492.0010-10

RAILEY, J. EXAMINER

18M2/0517  
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ART UNIT PAPER NUMBER

1804

DATE MAILED: 05/17/94

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 24 JAN, 15 MAR 1994 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 4 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- |   |   |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.                 | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152.       |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474.     | 6. <input type="checkbox"/>   |

Part II SUMMARY OF ACTION

1. ☒ Claims 11 AND 12 are pending in the application.

Of the above, claims 11 AND 12 are withdrawn from consideration.

- BEST AVAILABLE COPY**
2. ☐ Claims have been cancelled.
3. ☐ Claims are allowed.
4. ☒ Claims 11 AND 12 are rejected.
5. ☐ Claims are objected to.
6. ☐ Claims are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 11 and 12 are rejected under 35 U.S.C. § 101 because the invention as claimed lacks patentable utility and as disclosed is inoperative. This rejection is maintained for reasons given in the previous office action, paper No. 7, mailed 30 July 1993. The previous office action held:

Applicant claims nucleic acid having the sequence of the HIV-1 LTR as well as this sequence labeled in various ways. Applicant cites for support the specification page 13, lines 6-15 and page 14, lines 11-19. Page 13, lines 6-15 does set forth what is being claimed, but does not demonstrate a utility for this sequence. On page 14, lines 11-19 the disclosure holds that DNA can be used for "cloned probes". In addition, page 15, lines 18-24, notes of "polypeptides themselves which can be expressed by the different DNAs of the instant inventions, particularly by the ORFs or fragments thereof." Page 17, lines 3-11, specifically states a use for the LTR sequences. By inserting the LTR into a vector, the LTR is "then active as a promoter enabling the efficient transcription and translation in a suitable host of the above defined DNA insert coding for a determined protein placed under its controls."

First, applicant has not demonstrated a utility for the HIV LTR sequences as a probe. How specific is the LTR for detecting HIV? Is there cross-hybridization with other retroviral LTRs, in particular to the HTLV types I and II?

Second, applicant's disclosure states on page 17 that when vectors having the HIV LTR are used to transform human cells, the polymerases of the cell "are capable of recognizing the LTRs of LAV [HIV-1]." However, applicant should be aware of the fact that the HIV-1 LTR is non-

functional as a promoter without the presence of the trans-acting factor tat. Consequently, applicant has not demonstrated a utility of the LTR sequences as promoters in the application as filed.

Lastly, applicant notes in the specification, in particular Figure 3, that the nucleic acid claimed lies partially at the 3' end of an open reading frame labeled "ORF-R". Applicant believes that the nucleic acid sequences claimed are translatable into protein having a distinct sequence, such protein thereby having various utilities as stated in the specification. However, applicant has not demonstrated that these nucleic acid sequences comprising the 3' end of "ORF-R" are indeed translated into proteins having a demonstrable utility. Therefore, the nucleic acids as claimed have no demonstrated utility.

Applicant's arguments filed 24 January 1994, paper No. 8, have been fully considered but they are not deemed to be persuasive. Applicant cites the M.P.E.P. at § 608.01(p) and decisions by the Court of Appeals, Federal circuit as support for utility of the invention as disclosed. On page 4 of applicant's response, applicant also states:

The claimed nucleic acid satisfies the "some" utility requirement as it is useful in hybridization assays to detect the presence or absence of HIV.

It is maintained however, that this utility is not demonstrated. The hybridization conditions which demonstrate a useful probe to detect HIV specifically are not set forth. HIV has not been specifically detected by using the nucleic acid sequence as claimed. Applicant is provided with a reference by Hahn et al. [Nature 312:166-169 (1984)] which demonstrates that at the time of the filing of the instant application, it was known that cross-hybridization occurs between the

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sequences of the LTR of HIV and those of other human retroviruses under certain hybridization conditions. Note Figure 4, the hybridization of the HIV probe with 1.0 kb restriction fragment representing the LTR of HTLV-I or HTLV-Ib. There may also be hybridization with the 1.0 kb restriction fragment of HTLV-II. Consequently, specification as filed fails to present any "useful" hybridization assays which discriminate between the presence of HIV and HTLV-I or HTLV-II.

The reference submitted by applicant, EP 0 245 459 B1 by Essex et al. is not being considered. Its submission is not in accordance with the provisions of 37 CFR 1.97 and 1.98.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-3014.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. F. Railey whose telephone number is (703) 308-0281.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Elizabeth C. Weimar*  
ELIZABETH C. WEIMAR  
SUPERVISORY PATENT EXAMINER  
ART UNIT 184

Johnny F. Railey II, Ph.D.  
April 16, 1994